

REMARKS

The above amendments and these remarks are responsive to the final Office action dated April 18, 2006, and support the accompanying Request for Continued Examination as a submission under 37 C.F.R. § 1.114(c). Claims 28-30, 33-41, 83-86, and 88-90 are pending in the application. Claim 83 is the only independent claim. In the Office action, the Examiner rejected (1) each of the pending claims under 35 U.S.C. § 112, second paragraph, as being indefinite, and (2) each of the pending claims under 35 U.S.C. § 102 or 103 as being anticipated and/or obvious. In particular, the Examiner rejected:

- Claims 28, 30, 37-41, 83, 85, 89, and 90 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,410,255 to Pollok et al. ("Pollok");
- Claims 83 and 88 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,689,565 to Nikiforov ("Nikiforov");
- Claims 29, 33, 84, and 86 under 35 U.S.C. § 103(a) as being unpatentable over Pollok alone or in combination with U.S. Patent No. 5,674,698 to Zarling et al., U.S. Patent No. 6,524,790 to Kopf-Sill et al., or U.S. Patent No. RE33,581 to Nicoli et al.; and
- Claims 34-36 and 83 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,586,193 to Yguerabide et al. ("Yguerabide") in view of Pollok.

Applicants traverse the rejections, contending that none of the pending claims is indefinite, anticipated, or obvious. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants want to patent now, applicants have (1) canceled claims 85 and 86, without prejudice, and (2) amended claims 28-30, 33-37, 39, 41, 83, 84, 88, and 90. However, applicants reserve the right to pursue the canceled and/or amended claims, in original or distinctly amended form, at a later time. Furthermore, applicants have presented

arguments showing that the pending claims are patentable over the cited references. Accordingly, applicants respectfully request reconsideration of the application in view of the amendments above and the remarks below, and prompt issuance of a Notice of Allowability covering all of the pending claims.

I. Request for Continued Examination

Applicants are submitting herewith a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114. This Request complies with the requirements of 37 C.F.R. § 1.114. In particular:

- (i) Prosecution in the application is closed, since the last Office action was a final Office action under 37 C.F.R. § 1.113.
- (ii) The Request is accompanied by a submission as set forth at 37 C.F.R. § 1.114(c), specifically, the amendments and remarks set forth herein.
- (iii) The Request is accompanied by the fee set forth at 37 C.F.R. § 1.17(e).

Accordingly, applicants respectfully request grant of their Request for Continued Examination.

II. Information Disclosure Statement

The Examiner stated that the Information Disclosure Statement (IDS) filed November 7, 2005, was not considered because the IDS listed a non-matching serial number (Serial No. 11/204,439) instead of the serial number of the present application (Serial No. 09/768,742). Applicants believe that the IDS in question is not related to the present application. In particular, applicants have viewed the transmittal associated with the IDS in question online, using PAIR, and find two transmittals in the same Image File Wrapper entry (Mail Room Date 11-07-2005). Applicants thus suggest that a second

transmittal and its associated materials, namely the IDS and a certified copy of a foreign priority document, were improperly associated with applicants' transmittal and response to Office action received at about the same time in the Patent Office. Accordingly, applicants respectfully request that both the errant IDS and foreign priority document be removed from the application file of the present application, for association with the patent application file listed on the second transmittal, namely Serial No. 11/204,439.

III. Claim Rejections - 35 U.S.C. § 112

The Examiner rejected all of the pending claims under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Examiner stated that in independent claim 83 it is unclear whether "the probe" refers to an antecedent "luminescent probe" recited earlier in the same claim.

Applicants traverse the rejection, contending that the meaning of "the probe" is clear and definite from the claim language.

Nevertheless, in a spirit of cooperation and for the reasons set forth above, applicants have amended the pending claims to replace each recitation of "luminescent probe" or "probe" with the term "luminophore." Support for the term luminophore is included in the application, for example, on page 22, line 21, to page 23, line 7. Applicants believe that these amendments to the claims fully address all Section 112 issues raised by the Examiner and thus that the indefiniteness rejections should be removed.

IV. Claim Rejections – 35 U.S.C. §§ 102 and 103

The Examiner rejected all of the pending claims under 35 U.S.C. § 102(e) or § 103(a) as being anticipated by or obvious over (1) Pollok alone or in combination with another reference and/or (2) Nikiforov.

Applicants traverse the rejections, contending that none of the cited references, taken alone or in combination, teaches or suggests every element of any of the pending claims.

Nevertheless, for the reasons set forth above, applicants have amended independent claim 83, which is the only independent claim pending in the application, as noted above. Claim 83 has been amended as follows:

83. (Currently Amended) A kit for detecting enzyme activity in a sample, the kit comprising:

an enzyme;

a **luminophore** ~~luminescent probe~~ bound to a substrate for the enzyme;

and

a particulate mass label distinct from the enzyme and capable of specifically binding to the substrate or a product of the substrate produced by action of the enzyme on the substrate, but not both, **the particulate mass label including a bead**;

wherein a luminescence property of the **luminophore** ~~probe~~ is sensitive to binding of the mass label to the substrate or product.

Claim 83 was rejected in the Office action over (A) Pollok alone, (B) Yguerabide and Pollok, and (C) Nikiforov. Claim 83 is patentable over each of the cited references because the cited references do not teach or suggest every element of claim 83, for the reasons set forth below.

A. Pollok

Claim 83 recites a “particulate mass label including a bead” and being “capable of specifically binding to the substrate or a product of the substrate produced by action of the enzyme on the substrate, but not both.” Pollok does not teach or suggest a kit with the recited particulate mass label.

Pollok relates to optical probes and assays. Figure 1 of Pollok, which is reproduced here to facilitate review, provides schematic representations of various embodiments of Pollok's probes. Each probe is stated to include a polypeptide 5 with a post-translational modification recognition site 6 and a protease site 7 for protease-based cleavage of the polypeptide. The polypeptide is attached to a probe moiety 1 that provides an optical probe for optical detection of changes to the structure of the polypeptide. In some cases, the polypeptide also may be attached to a solid surface 4, such as a bead.

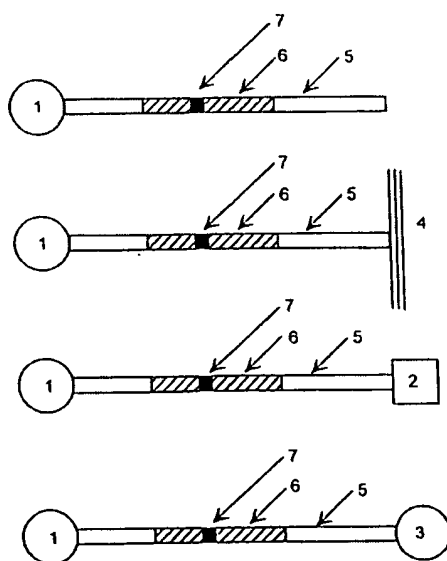


FIG. 1

In the Office action, the Examiner specifically cited column 25, lines 4-6, 9, and 30-36, of Pollok to reject claim 83. This section of Pollok involves fluorescence polarization assays that measure changes in the fluorescence anisotropy of an optical probe produced by protease cleavage. The optical probe is disclosed to have the structure presented above in Figure 1, for example, a polypeptide attached to both a bead and to a fluorescence moiety. Both the substrate of the protease (intact polypeptide) and one of the cleavage products produced by action of the protease on the polypeptide remain attached to the bead during the assay. Accordingly, Pollok discloses a bead attached to both a substrate and a product of the substrate. In contrast, claim 83 recites a particulate mass label capable of specifically binding to the substrate or a product of the substrate produced by action of the enzyme on the substrate, but not both. Therefore, for at least these reasons, claim 83 should be allowed. Claims 28-30, 33-41, 84, and 88-90, which depend from claim 83, also should be patentable over Pollok for at least the same reasons as claim 83.

B. Yguerabide and Pollok

Claim 83 also was rejected as being unpatentable over a combination of Yguerabide and Pollok. Neither Yguerabide nor Pollok, taken alone or in combination, teaches or suggests a kit with the recited particulate mass label.

Yguerabide relates to analyte assays with particulate labels. In the Office action, the Examiner asserted that Yguerabide discloses all elements of claim 83 except a luminescent probe bound to a substrate for an enzyme, citing column 86, line 66, to column 87, line 8, of Yguerabide. The cited section of Yguerabide relates to cleavage assays in which a light scattering particle is attached to a substrate for a cleavage

enzyme or ribozyme. However, as in Pollok, and in contradiction to claim 83, the light scattering particle is attached both to the substrate and to a product of the substrate produced by cleavage of the substrate. In contrast, claim 83 recites a particulate mass label capable of specifically binding to the substrate or a product of the substrate produced by action of the enzyme on the substrate, but not both. Accordingly, neither Yguerabide nor Pollok (see subsection A above) teaches or suggests the recited particulate mass label of claim 83. Claim 83 thus should be allowed. Claims 34-36, which depend from claim 83 and also were rejected over Yguerabide and Pollok, also should be patentable over Yguerabide and Pollok for at least the same reasons as claim 83.

C. Nikiforov

Claim 83 was rejected as being anticipated by Nikiforov. However, applicants submit that claim 83 is patentable over Nikiforov because (1) the reference does not teach or suggest every element of claim 83, and (2) Nikiforov does not constitute prior art to applicants' earliest filing date for the subject matter of claim 83.

Claim 83 recites a particulate mass label "including a bead." Nikiforov does not teach or suggest a kit with a particulate mass label including a bead.

Nikiforov discloses assay methods and systems. The assay method is presented schematically in Figure 1 of Nikiforov, which is reproduced here to facilitate review:

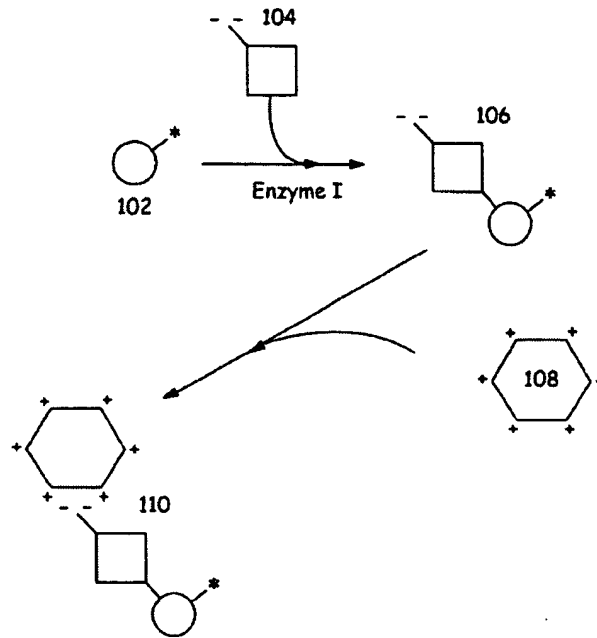


Figure 1

The assay involves a fluorescently labeled first reagent 102 that is contacted with an enzyme (Enzyme I) in the presence of a charged group 104 to create a charged product 106. The charged product is contacted with a polyion 108 that associates with charged product 106 to reduce the rotational diffusion rate of the product relative to first reagent 102. Nikiforov discloses polyion 108 to be a polycationic polymer, such as a polyamino acid (i.e., polylysine, polyhistidine, polyarginine, or copolymers thereof (claim 18)) or “a polymer having multivalent metal cations associated therewith” (claim 19). However, Nikiforov does not teach or suggest the polyion to be a particulate mass label including a bead, as recited by claim 83. For at least these reasons, claim 83 should be allowed. Claim 88, which depends from claim 83 and which also was rejected as being anticipated by Nikiforov, also should be patentable over Nikiforov for least the same reasons as claim 83.

Applicants also believe that Nikiforov does not qualify as prior art to claim 83 under 35 U.S.C. § 102 or § 103. In particular, the subject matter of claim 83 should be given a priority date of October 20, 1998, because the present application claims priority from U.S. Provisional Patent Application Serial No. 60/104,964, which was filed October 20, 1998 and which supports claim 83. Therefore, the rejection of claim 83 over Nikiforov should be removed for this additional reason.

V. Patentably Distinct Limitations of the Dependent Claims

Many or all of the dependent claims also add limitations that further distinguish the claimed invention from the prior art. For example, claim 34 recites “the kit further comprising a second mass label capable of specifically binding to (1) the substrate, (2) a complex formed by binding of the luminophore to the substrate, (3) the product, (4) the first mass label, or (5) a combination thereof.” None of the cited references, taken alone or in combination, teaches or suggests a first mass label and a second mass label. Even more particularly, none of the cited references teaches or suggests a second mass label “capable of specifically binding to at least two first mass labels,” as recited in part by claim 35, or a second mass label including “avidin, biotin, lectin, sugar, an immunological binding partner, or a combination thereof,” as recited by claim 36. Therefore, dependent claims 34-36, among others, also should be allowed for these additional reasons.

VI. Other Claim Amendments

The present communication also makes other amendments to the claims that were not described above. For example, claim 29 was amended to replace “unbound probe” with “luminophore bound to the substrate in the absence of the mass label” to clarify the relationship between photoluminescence lifetime and rotational correlation times

recited by the claim. In addition, each of claims 34 and 36 was amended to replace "at least one of" with an alternative recitation having the same intended meaning. Moreover, claim 35 was amended to clarify that the second mass label may form cross-links between molecules of the substrate or product. Furthermore, claim 84 was amended to recite aspects of the bead (rather than the particulate mass label) and to replace "polyacrylnitrile" with the more commonly used term "polyacrylonitrile" of the same meaning.

VII. Conclusion

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

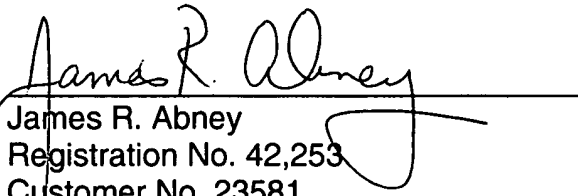
Respectfully submitted,

KOLISCH HARTWELL, P.C.

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on October 18, 2006.


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